

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)



Complete if Known

Application Number	10/815,262
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1633
Examiner Name	Hill, Kevin

Sheet 1 of 11

Attorney Docket No: 875.074US1

**US PATENT DOCUMENTS**

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Filing Date If Appropriate
	US-20010034349A1	10/25/2001	Boucher, Jr., R. C.	02/20/2001
	US-20010041682A1	11/15/2001	Stutts, III, M. J., et al.	05/07/2001
	US-20020099023A1	07/25/2002	Boucher, Jr., Richard C.	03/01/2002
	US-20020115619A1	08/22/2002	Rubenstein, R. C., et al.	10/04/2001
	US-20020128203A1	09/12/2002	Schild, L.	09/19/2001
	US-20020132770A1	09/19/2002	Caplan, M. T., et al.	10/12/2001
	US-20020156057A1	10/24/2002	Bubien, J. K.	04/19/2002
	US-20020158255A1	10/31/2002	Boucher, Jr., R. C.	04/12/2002
	US-20020165239A1	11/07/2002	Boucher, Jr., R. C.	04/12/2002
	US-20030087818A1	05/08/2003	Jiang, Y., et al.	02/01/2002
	US-20040248301A1	12/09/2004	Engelhardt, J. F., et al.	04/30/2004
	US-20050037497A1	02/17/2005	Engelhardt, J. F., et al.	03/31/2004
	US-20050158281A1	07/21/2005	Chamberlain, Jeffrey S., et al.	11/15/2007
	US-20050181423A1	08/18/2005	Barak, L. S., et al.	03/21/2005
	US-20050255087A1	11/17/2005	Engelhardt, J. F., et al.	02/15/2005
	US-4,501,729	02/26/1985	Boucher, R. C., et al.	12/13/1982
	US-5,292,498	03/08/1994	Boucher, Jr., R. C.	06/19/1991
	US-5,512,269	04/30/1996	Molina y Vedia, L. M., et al.	06/09/1993
	US-5,628,984	05/13/1997	Boucher, Jr., R. C.	07/31/1995
	US-5,635,160	06/03/1997	Stutts, III, M. J., et al.	06/07/1995
	US-5,651,957	07/29/1997	Molina y Vedia, L. M., et al.	05/02/1995
	US-5,656,256	08/12/1997	Boucher, R. C., et al.	12/14/1994
	US-5,683,675	11/04/1997	Molina y Vedia, L. M., et al.	05/02/1995
	US-5,716,931	02/10/1998	Molina y Vedia, L. M., et al.	05/02/1995
	US-5,725,842	03/10/1998	Boucher, Jr., R. C., et al.	01/05/1996
	US-5,801,030	09/01/1998	McVey, D. L., et al.	09/01/1995
	US-5,849,706	12/15/1998	Molina y Vedia, L. M., et al.	01/28/1998
	US-5,855,918	01/05/1999	Mrsny, R. J., et al.	09/12/1996
	US-5,876,700	03/02/1999	Boucher, Jr., R. C., et al.	01/31/1997
	US-5,902,567	05/11/1999	Boucher, Jr., R. C.	12/30/1996
	US-5,935,555	08/10/1999	Stutts, III, M. J., et al.	05/08/1977
	US-6,022,527	02/08/2000	Boucher, Jr., R. C., et al.	07/13/1999
	US-6,033,688	03/07/2000	Mrsny, R. J., et al.	09/02/1997
	US-6,037,177	03/14/2000	Snyder, R.	08/08/1997
	US-6,133,247	10/17/2000	Boucher, Jr., R. C.	07/24/1996
	US-6,143,279	11/07/2000	Boucher, Jr., R. C., et al.	08/28/1998
	US-6,214,536	04/10/2001	Boucher, Jr., R. C.	11/04/1999
	US-6,235,266	05/22/2001	Stutts, III, M. J., et al.	04/30/1999
	US-6,264,975	07/24/2001	Boucher, Jr., Richard C.	10/20/1999
	US-6,323,187	11/27/2001	Yerxa, B. R., et al.	05/21/1999

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

<b>Application Number</b>	10/815,262
<b>Filing Date</b>	March 31, 2004
<b>First Named Inventor</b>	Engelhardt, John
<b>Group Art Unit</b>	1633
<b>Examiner Name</b>	Hill, Kevin

Sheet 2 of 11

Attorney Docket No: 875.074US1

**US PATENT DOCUMENTS**

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Filing Date If Appropriate
	US-6,416,759	07/09/2002	Firestone, G. L., et al.	09/30/1999
	US-6,420,347	07/16/2002	Jacobus, K. M., et al.	03/27/1997
	US-6,451,288	09/17/2002	Boucher, Jr., R. C., et al.	08/24/2000
	US-6,475,509	11/05/2002	Boucher, Jr., R. C.	07/19/2000
	US-6,586,416	07/01/2003	Bubien, J. K.	04/19/2002
	US-6,607,741	08/19/2003	Boucher, Jr., R. C.	04/12/2002
	US-6,613,345	09/02/2003	Boucher, Jr., R. C.	04/12/2002
	US-7,060,497	06/13/2006	Nakai, H., et al.	03/01/2001
	US-7,241,447	07/10/2007	Engelhardt, J. F., et al.	10/06/2000

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	T <sup>2</sup>
	AU-4091299	12/06/1999	Englehart, John F., et al.	
	CA-2302627	09/23/2001	Yves, B., et al.	
	EP-0041682A1	12/16/1981	Shutske, G. M., et al.	
	EP-0132770A1	02/13/1985	Grau, U.	
	EP-0158255A2	10/16/1985	Giordano, C., et al.	
	EP-1486567A1	12/15/2004	Kleinschmidt, J., et al.	
	WO-0075365A1	12/14/2000	Engelhardt, John F., et al.	
	WO-0075365A3	12/14/2000	Engelhardt, John F., et al.	
	WO-01025465A1	04/12/2001	Engelhardt, J. F., et al.	
	WO-02087306A2	11/07/2002	Callamaras, N., et al.	
	WO-0224172A1	03/28/2002	Vanderbist, F., et al.	
	WO-0224177A2	03/28/2002	Schild, L., et al.	
	WO-03006616A2	01/23/2003	Engelhardt, J. F., et al.	
	WO-03057847A2	07/17/2003	Shuster, S. J., et al.	
	WO-03095667a2	11/20/2003	Arexis, , et al.	
	WO-04089423A2	10/21/2004	Engelhardt, J. F., et al.	
	WO-04089423A3	10/21/2004	Engelhardt, J. E., et al.	
	WO-04090145A3	10/21/2004	Engelhardt, J. F.	
	WO-2004112727A2	12/29/2004	ARBETMAN, A. E., et al.	
	WO-2005116224A2	12/08/2005	Bohn, , et al.	
	WO-2005119251A2	12/15/2005	KRAUSE, K., et al.	
	WO-2007127464A2	11/08/2007	ENGELHARDT, J F., et al.	
	WO-4090145A2	10/21/2004	Engelhardt, J. F., et al.	
	WO-9610402A1	04/11/1996	Van Dyke, Knox	
	WO-9853839A2	12/03/1998	Stoven, V., et al.	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

<b>Application Number</b>	10/815,262
<b>Filing Date</b>	March 31, 2004
<b>First Named Inventor</b>	Engelhardt, John
<b>Group Art Unit</b>	1633
<b>Examiner Name</b>	Hill, Kevin

Sheet 3 of 11

Attorney Docket No: 875.074US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-Issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		"Application Serial No 11/796,605 (Atty Ref 875.124US1), Preliminary Amendment 09-11-07", 6 pgs	
		"Application Serial No 04749597.3 (Atty Ref 875.085EP1), Office Action 11-20-06", 3 pgs	
		"Application Serial No 04749597.3 (Atty Ref 875.085EP1), Office Action mailed 03-28-06", 9 pgs	
		"Application Serial No 04749597.3 (Atty Ref 875.085EP1), Response filed 09-06-07 to Office Action 11-20-06", 6 pgs	
		"Application Serial No 04749597.3 (Atty Ref 875.085EP1), Response filed 10-06-06 to Office Action mailed 03-28-06", 28 pgs	
		"Application Serial No 782966 (Atty Ref 87.032AU1), Response filed 07-07-05 to Foreign Office Action 11-18-04", 15 pgs	
		"Application Serial No 782966 (Atty Ref 875.032AU1) Examiner Report Received 11-18-04", 3 pgs	
		"Application Serial No 782966 (Atty Ref 875.032AU1), Foreign office Action 07-18-05", 2 pgs	
		"Application Serial No. 00944624.6 (Atty Ref 875.032EP1), Foreign Office Action 03-04-05", 5 pgs	
		"Application Serial No. 00944624.6 (Atty Ref 875.032EP1), Foreign Office Action 08-05-03", 3 pgs	
		"Application Serial No. 00944624.6 (Atty Ref 875.032EP1), Response filed 02-16-04 to Office Action Mailed 08-05-03", 25 pgs	
		"Application Serial No. 00944624.6 (Atty Ref 875.032EP1), Response filed 08-26-05 to Office Action mailed 03-04-05", 31 pgs	
		"Application Serial No. 04749619.5 (Atty Ref 875.074EP1), Office Action mailed 03-28-06", 8 pgs	
		"Application Serial No. 04749619.5 (Atty Ref 875.074EP1), Office Action mailed 11-20-06", 4 pgs	
		"Application Serial No. 04749619.5 (Atty Ref 875.074EP1), Response filed 09-07-07 to Office Action mailed 11-20-06", 28 pgs	
		"Application Serial No. 04749619.5 (Atty Ref 875.074EP1), Response filed 10-17-06 to Office Action mailed 03-28-06", 17 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Advisory Action mailed 11-03-2004", 3 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Amendment filed 08-03-2005", 13 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Amendment filed 11-18-2004", 11 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Final Office Action mailed 02-24-2003", 11 pgs	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional) <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

<b>Application Number</b>	10/815,262
<b>Filing Date</b>	March 31, 2004
<b>First Named Inventor</b>	Engelhardt, John
<b>Group Art Unit</b>	1633
<b>Examiner Name</b>	Hill, Kevin

Sheet 4 of 11

Attorney Docket No: 875.074US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Final Office Action mailed 06-18-2004", 8 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Non Final Office Action mailed 01-07-2005", 10 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Non Final Office Action mailed 06-26-2002", 13 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Non Final Office Action mailed 08-12-2003", 8 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Notice of Allowance mailed 09-12-2005", 10 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Preliminary Amendment filed 10-12-2000", 2 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Response filed 01-12-2004 to Non Final Office Action mailed 08-12-2003", 12 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Response filed 05-18-2005 to Non Final Office Action mailed 01-07-2005", 14 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Response filed 05-30-2003 to Final Office Action mailed 02-24-2003", 13 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Response filed 10-18-2004 to Final Office Action mailed 06-18-2004", 13 pgs	
		"Application Serial No. 09/689,136 (Atty. Ref. 875.032US1) Response filed 11-26-2002 to Non Final Office Action mailed 06-26-2002", 14 pgs	
		"Application Serial No. 10/815,557 (Atty. Ref. 875.085US1) Non Final Office Action mailed 05-21-2007", 24 pgs	
		"Application Serial No. 10/815,557 (Atty. Ref. 875.085US1) Response filed 08-21-2007 to Non Final Office Action mailed 05-21-2007", 22 pgs	
		"Application Serial No. 10/815557 (Atty. Ref. 875.085US1 ), Final-Office Action Mailed 11-14-2007", 29 pgs	
		"Application Serial No. 11/301,601 (875.032US2), Non-Final Office Action mailed 07/12/2007", 29 pgs.	
		"Application Serial No. 11/301,601 (Atty Ref 875.032US2), Response filed 10/11/07 to Non-Final Office Action mailed 7/12/07", 14 pages	
		"Application Serial No. 11/301,601 (Atty. Ref. 875.032US3) Preliminary Amendment filed 08-07-2007", 9 pgs	
		"Application Serial No. 11/301,601, (Atty Ref 875.032US2) Non-Final Office Action mailed 7/12/2007", 29 pgs	
		"Application Serial No. 11/301,601, (Atty Ref 875.032US2) Preliminary Amendment filed 12/13/2005", 9 pgs	
		"Application Serial No. 11/301,601, (Atty Ref 875.032US2) Response filed 8/11/2007 Non-Final Office Action mailed 7/12/2007", 14 pgs	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.<sup>1</sup> Applicant's unique citation designation number (optional) <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

<b>Application Number</b>	10/815,262
<b>Filing Date</b>	March 31, 2004
<b>First Named Inventor</b>	Engelhardt, John
<b>Group Art Unit</b>	1633
<b>Examiner Name</b>	Hill, Kevin

Sheet 5 of 11

Attorney Docket No: 875.074US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		"Application Serial No. 11/301601 (Atty Ref. 875.032US2) Final Office Action mailed 12/13/2007", 15 pgs	
		"Application Serial No. 11/890,777, (Atty Ref 875.032US3) Preliminary Amendment filed 8/7/2007", 9 pgs	
		"Application Serial No. 501645/01 (Atty Ref 875.032JP1), Preliminary Amendment filed 05-31-07", 12 pgs	
		"Enzyme database entry for EC number 3.4.22", <u>u</u> [online]. Retrieved from the Internet: < <a href="http://ca.expasy.org/enzyme/3.4.22">http://ca.expasy.org/enzyme/3.4.22</a> >, (June 19, 2007), 2 pgs.	
		"International Application Serial No. PCT/US 00/15700 (Atty Ref 875.032WO1), International Search Report 12-21-00", (12-21-00), 9 pgs	
		"International Application Serial No. PCT/US 00/15700 (Atty Ref 875.032WO1), Written Opinion 08-01-01", (08/01/2001), 7 pgs	
		"International Application Serial No. PCT/US2007/010434 (Atty Ref 875.124WO1), International Search Report mailed 12-05-07", 11 pgs.	
		"International Application Serial No. PCT/US2007/010434 (Atty Ref 875.124WO1), Written Opinion mailed 12-05-07", 19 pgs	
		"International Search Report for corresponding PCT Application No. PCT/US2004/009950 mailed 03-08-05", (Attorney Docket No. 875.085WO1), 8 pgs.	
		"Written Opinion for corresponding PCT Application No. PCT/US2004/009950", (Attorney Docket No. 875.085WO1), (03/08/2005), 15 pgs.	
		"Written Opinion for corresponding PCT Application No. PCT/US2004/010045", (Attorney Docket No. 875.074WO1), (January 10, 2005), 15 pgs	
		AUDIGE, A. , et al., "Epithelial sodium channel (ENaC) subunit mRNA and protein expression in rats with puromycin aminonucleoside-induced nephrotic syndrome.", <u>Clinical Sci.</u> , 104(4), (2003), 389-395	
		AUERBACH, S. D., et al., "Human Amiloride-Sensitive Epithelial Na <sup>+</sup> Channel $\gamma$ Subunit Promoter: Functional Analysis and Identification of a Polypurine-Polypyrimidine Tract With the Potential for Triplex DNA Formation", <u>Biochem. J.</u> , 347, (2000), 105-114	
		BAINES, D. L., et al., "Effect of LPS-Induced NF-kB Activity on the Transcriptional Response of a 5' Flanking Region of the $\alpha$ ENaC Gene", <u>Experimental Biology 2003 - Translating the Genome</u> , Abstract No. 5860 ( <a href="http://www.biosis-select.org/faseb/data/FASEB005860.html">http://www.biosis-select.org/faseb/data/FASEB005860.html</a> ), (2003), 1 pg.	
		BARUCHEL, S. , et al., "The role of oxidative stress in disease progression in individuals infected by the human immunodeficiency virus.", <u>J Leukoc Biol.</u> , 52(1), (Jul., 1992), 111-4	
		BEUTLER, K. T., et al., "Long-Term Regulation of ENaC Expression in Kidney by Angiotensin II", <u>Hypertension</u> , 41, (2003), 1143-1150	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional) <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

<b>Application Number</b>	10/815,262
<b>Filing Date</b>	March 31, 2004
<b>First Named Inventor</b>	Engelhardt, John
<b>Group Art Unit</b>	1633
<b>Examiner Name</b>	Hill, Kevin

Sheet 6 of 11

Attorney Docket No: 875.074US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BILLINGTON, D. , et al., "Dissection of hepatic receptor-mediated endocytic pathways using self-generated gradients of iodixanol (Optiprep).", <u>Anal. Biochem.</u> , 258(8), (1998),251-258	
		BOHL, D. , et al., "Control of erythropoietin delivery by doxycycline in mice after intramuscular injection of adeno-associated vector.", <u>Blood</u> , 92(5), (1998),1512-1517	
		BOOTH, R. E., et al., "Targeted Degradation of ENaC in Response to PKC Activation of the ERK1/2 Cascade", <u>Am. J. Physiol. Renal Physiol.</u> , 284, (2003),F938-F947	
		BRUNO, T. , et al., "Levels of Expression of hRPB11, a core subassembly subunit of human RNA polymerase II, affect doxorubicin sensitivity and cellular differentiation", <u>FEBS Letters</u> 427, (1998),241-246	
		BUBIEN, J. K., et al., "Expression and regulation of normal and polymorphic epithelial sodium channel by human lymphocytes", <u>J. Biol. Chem.</u> , 276(11), (2001),8557-8566	
		BUFFINTON, G. D., et al., "Oxidative stress in lungs of mice infected with influenza A virus", <u>Free Radic Res Commun.</u> , 16(2), (1992),99-110	
		CAI, J. , et al., "Inhibition of influenza infection by glutathione.", <u>Free Radic Biol Med.</u> , 34(7), (Apr. 1, 2003),928-36	
		DOLLARD, S. C., et al., "Enhanced responsiveness to nuclear factor kappa B contributes to the unique phenotype of simian immunodeficiency virus variant SIVsmmPBj14.", <u>J Virol.</u> , 68(12), (Dec., 1994),7800-9	
		DROGE, W. , et al., "HIV-induced cysteine deficiency and T-cell dysfunction--a rationale for treatment with N-acetylcysteine", <u>Immunol Today.</u> , 13(6), (Jun., 1992),211-4	
		ECELBARGER, C. A., et al., "Regulation of the Abundance of Renal Sodium Transporters and Channels by Vasopressin", <u>Experimental Neurology</u> , 171, (2001),227-234	
		ECK, et al., <u>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</u> , 9th Edition, Chapter 5, McGraw-Hill, NY.	
		ENGELHARDT, J. , et al., "ADENO-ASSOCIATED VIRUS VECTORS", <u>U.S. Provisional Application SN 60/086,166</u> , filed May 20, 1998 (875.005PRV).	
		ENGELHARDT, JOHN , et al., "COMPOUNDS AND METHODS TO ENHANCE ADENO-ASSOCIATED VIRUS TRANSDUCTION", <u>U.S. Provisional Application SN 60/138,188</u> , filed June 8, 1999.	
		ENGELHARDT, JOHN , et al., "COMPOUNDS AND METHODSD TO ENHANCE ADENO-ASSOCIATED VIRUS TRANSDUCTION", <u>U.S. Provisional Application SN 60/201,089</u> filed May 2, 2000.	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/815,262
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1633
Examiner Name	Hill, Kevin

Sheet 7 of 11

Attorney Docket No: 875.074US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ENGELHARDT, JOHN, et al., "ENHANCEMENT OF MUSCLE GENE DELIVERY WITH PSEUDOTYPED AAV-5 CORRELATES WITH MYOBLAST DIFFERENTIATION", <u>U.S. Provisional Application SN 60/305,204 filed July 13, 2001.</u>	
		ENGLEHARDT, JOHN, "COMPOUNDS AND METHODS FOR PHARMICO-GENE THERAPY OF EPITHELIAL SODIUM CHANNEL ASSOCIATED DISORDERS", <u>U.S. Provisional Application SN 60/512,347 filed October 16, 2003.</u>	
		ENGLEHARDT, JOHN, et al., "COMPOUNDS AND METHODS TO ENHANCE rAAV TRANSDUCTION", <u>U.S. Provisional Application SN 60/459,323 filed March 31, 2003.</u>	
		ENGLEHARDT, JOHN, et al., "PSEUDOTYPED ADENO-ASSOCIATED VIRUSES AND USES THEREOF", <u>U.S. Patent Application SN 10/194,421 filed July 12, 2002.</u>	
		FALLIN, R. A., et al., "PMA-Induced Inhibition of Amiloride-Sensitive Sodium Absorption is Partially Mediated by ERK1/2 Activation", <u>The FASEB Journal</u> , 17(5) (Abstracts Part II), Abstract No. 585-19,(2003),A915	
		GADALLAH, M. F., et al., "Epithelial Sodium Channel-Dependent Hypertension: An Emerging Syndrome", <u>Journal of the American Society of Nephrology</u> , 10 (Abstracts Issue), Abstract No. A1842,(1999),365A	
		GADALLAH, M. F., et al., "Preservation of Renal Function in Patients With Hypertension and Chronic Renal Impairment; Revisited", <u>Journal of the American Society of Nephrology</u> , 10 (Abstracts Issue), Abstract No. A1841,(1999),365A	
		GORMLEY, K., et al., "Regulation of the Epithelial Sodium Channel by Accessory Proteins", <u>Biochem. J.</u> , 371, (2003),1-14	
		GRAHAM, J. M., et al., "Iodixanol--a new density gradient medium for the dissection of the endosomal compartment", <u>Z Gastroenterol.</u> , 34 Suppl 3, (1996),76-8	
		GRAHAM, J., "Purification of peroxisomes using a density barrier in a swinging-bucket rotor.", <u>ScientificWorldJournal</u> , 2, (May 22, 2002),1400-3	
		GRAHAM, J., et al., "The preparation of subcellular organelles from mouse liver in self-generated gradients of iodixanol", <u>Anal. Biochem.</u> , 220(2), (1994),367-73	
		HUMMLER, E., et al., "Genetic Disorders of Membrane Transport - V. The Epithelial Sodium Channel and its Implication in Human Diseases", <u>American Journal of Physiology, Gastrointestinal and Liver Physiology</u> , 276, (1999),G567-G571	
		HUNZIKER, et al., "Review - Perspectives: toward a peptide-based vaccine against hepatitis C virus", <u>Molecular Immunol.</u> , 38, (2001),475-484	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

<b>Application Number</b>	10/815,262
<b>Filing Date</b>	March 31, 2004
<b>First Named Inventor</b>	Engelhardt, John
<b>Group Art Unit</b>	1633
<b>Examiner Name</b>	Hill, Kevin

Sheet 8 of 11

Attorney Docket No: 875.074US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		JIANG, Q. , et al., "Cellular Heterogeneity of CFTR Expression and Function in the Lung: Implications for Gene Therapy of Cystic Fibrosis", <u>European Journal of Human Genetics</u> , 6, (Jan., 1998),12-31	
		JOHNSON, L. G. , et al., "Efficiency of gene transfer for restoration of normal airway epithelial function in cystic fibrosis", <u>Nature Genetics</u> 2, (1992),21-25	
		JORGENSEN, M. J. , et al., "Expression of Completely y-Carboxylated Recombinant Human Prothrombin", <u>The Journal of Biological Chemistry</u> , 262(14), (1987),6729-6734	
		KAMYNINA, E. , et al., "Concerted Action of ENaC, Nedd4-2, and Sgk1 in Transepithelial Na <sup>+</sup> Transport", <u>Am. J. Physiol. Renal Physiol.</u> , 283, (2002),F377-F387	
		KANNAN, R. , et al., "Impairment of conjunctival glutathione secretion and ion transport by oxidative stress in an adenovirus type 5 ocular infection model of pigmented rabbits.", <u>Free Radic Biol Med.</u> , 37(2), (Jul. 15, 2004),229-38	
		KELLENBERGER, et al., "Epithelial Sodium Channel/Degenerin Family of Ion Channels: A Variety fo Functions for a Shared Structure", <u>Physiological Review</u> , 82, (2002),735-767	
		LAMBETH, DAVID J., "Nox enzymes and the biology of reactive oxygen", <u>NATURE REVIEWS, IMMUNOLOGY</u> Mar 2004, vol. 4, no.3, March 2004, (2004-03, pages 181-189, XP002450232, (03/2004),9	
		LECHARDEUR, et al., "Intracellular Barriers to Non-Viral Gene Transfer", <u>Curr. Gene Therapy</u> , 2, (2002),183-194	
		LI, Q. , et al., "Nox2 and Rac1 regulate H2O2-dependent recruitment of TRAF6 to endosomal interleukin-1 receptor complexes", <u>Mol Cell Biol.</u> , 26(1), (Jan., 2005),140-54	
		LIN, H. C., et al., "Prediction of tyrosine sulfation sites in animal virus", <u>Biochemical And Biophysical Research Communications</u> ,312(4), (12/26/2003),1154-1158	
		LOGUERCIO, C. , et al., "Oxidative stress in viral and alcoholic hépatitis.", <u>Free Radic Biol Med.</u> , 34(1), (Jan. 1, 2003),1-10	
		MAITRA, R. , et al., "Increased Functional Cell Surface Expression of CFTR and deltaF508-CFTR by the Anthracycline doxorubicin", <u>Am. J. Physiol. Cell Physiol.</u> , 280, (May, 2001),C1031-C1037	
		MALIK, B. , et al., "ENaC Degradation in A6 Cells by the Ubiquitin-Proteosome Proteolytic Pathway", <u>The Journal of Biological Chemistry</u> , 276(16), (Apr. 20, 2001),12903-12910	
		MARSHALL, E. , "Gene Therapy's Growing Plans", <u>Science</u> 269(5227), (1995),1050-1055	
		MATALON, S. , et al., "Lung Edema Clearance: 20 Years of Progress - Invited Review: Biophysical Properties of Sodium Channels in Lung Alveolar Epithelial Cells", <u>J. Appl. Physiol.</u> , 93, (2002),1852-1859	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. † Applicant's unique citation designation number (optional) ‡ Applicant is to place a check mark here if English language Translation is attached



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

<b>Application Number</b>	10/815,262
<b>Filing Date</b>	March 31, 2004
<b>First Named Inventor</b>	Engelhardt, John
<b>Group Art Unit</b>	1633
<b>Examiner Name</b>	Hill, Kevin

Sheet 9 of 11

Attorney Docket No: 875.074US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		MCFADDEN, G. , "Even viruses can learn to cope with stress.", <u>Science</u> , 279(5347), (Jan. 2, 1998),40-1	
		MIHM, S. , et al., "Inhibition of HIV-1 replication and NF-kappa B activity by cysteine and cysteine derivatives.", <u>AIDS</u> , 5(5), (May, 1991),497-503	
		MIRSHAHI, M. , et al., "Paradoxical Effects of Mineralocorticoids on the Ion Gated Sodium Channel in Embryologically Diverse Cells", <u>Biochemical and Biophysical Research Communications</u> , 270, (2000),811-815	
		NAKAMURA, H. , et al., "Redox imbalance and its control in HIV infection", <u>Antioxid Redox Signal.</u> , 4(3), (Jun., 2002),455-64	
		NAKAYAMA, M. , et al., "Hypomethylation Status of CpG Sites at the Promoter Region and Overexpression of the Human MDR1 Gene in Acute Myeloid Leukemias", <u>Blood</u> , 92(11), (1998),4296-4307	
		NEWMAN, G. W., et al., "Opposing regulatory effects of thioredoxin and eosinophil cytotoxicity-enhancing factor on the development of human immunodeficiency virus 1.", <u>J Exp Med.</u> , 180(1), (Jul. 1, 1994),359-63	
		ODA, T. , et al., "Oxygen radicals in influenza-induced pathogenesis and treatment with pyran polymer-conjugated SOD.", <u>Science</u> , 244(4907), (May 26, 1989),974-6	
		ORKIN, S. H., et al., "Report and recommendation of the Panel to Assess the NIH Investment in Research on Gene Therapy", [on-line]. [retrieved 2007-7-6]. Retrieved from the Internet: <URL: file:///E:\Enablement Rejections\Generally usefu art\wwwnihgov-news-panelreph.htm>,(December 7, 1995),39 pgs.	
		PLONNE, D. , et al., "Separation of the intracellular secretory compartment of rat liver and isolated rat hepatocytes in a single step using self-generating gradients of iodoxanol.", <u>Anal Biochem.</u> , 276(1), (Dec. 1, 1999),88-96	
		ROSS, G. , et al., "Gene Therapy in the United States: A Five-Year Status Report", <u>Human Gene Therapy</u> , 7, (1996),1781-1790	
		ROTIN, D. , "Regulation of the Epithelial Sodium Channel (ENaC) by Accessory Proteins", <u>Current Opinion in Nephrology and Hypertension</u> , 9, (2000),529-534	
		ROTIN, D. , et al., "Trafficking and Cell Surface Stability of ENaC", <u>Am. J. Physiol. Renal Physiol.</u> , 281, (2001),F391-F399	
		RUBANYI, G. M., "The Future of Human Gene Therapy", <u>2001 Mol Aspects Med.</u> 22, 113-142	
		SAKAI, et al., "Cloning and functional expression of a novel degenerin-like Na <sup>+</sup> channel gene in mammals", <u>J. Physiol</u> 519, (1999),323-333	
		SANLIOGLU, S , et al., "Cellular redox state alters recombinant adeno-associated virus transduction through tyrosine phosphate pathways", <u>GENE THERAPY</u> Aug 1999. vol. 6, no. 8 pages 1427-1437, XP002450231, (08/1999),11	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional) <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

<b>Application Number</b>	10/815,262
<b>Filing Date</b>	March 31, 2004
<b>First Named Inventor</b>	Engelhardt, John
<b>Group Art Unit</b>	1633
<b>Examiner Name</b>	Hill, Kevin

Sheet 10 of 11

Attorney Docket No: 875.074US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		SANLIOGLU, S. , et al., "Endocytosis and nuclear trafficking of adeno-associated virus type 2 are controlled by rac1 and phosphatidylinositol-3 kinase activation", <u>Journal of Virology</u> , 74(9), (Oct 2000),9184-9196	
		SANLIOGLU, et al., "NOVEL APPROACHES TO AUGMENT ADENO-ASSOCIATED VIRUS TYPE-2 ENDOCYTOSIS AND TRANSDUCTION", <u>VIRUS RESEARCH AND TRANSDUCTION</u> ,104(1), (Aug. 2004),51-59	
		SCHAEFER, et al., "Molecular cloning, functional expression and chromosomal localization of an amiloride-sensitive Na <sup>+</sup> channel from human small intestine", <u>FEBS Letters</u> 471, (2000),205-210	
		SCHRECK, R. , et al., "Antioxidants selectively suppress activation of NF-kappa B by human T-cell leukemia virus type I Tax protein", <u>J Virol.</u> , 66(11), (Nov., 1992),6288-93	
		SCHWARZ, K. , "Oxidative stress during viral infection: a review.", <u>Free Radic Biol Med.</u> , 21(5), (1996),641-9	
		SHISLER, J. L., et al., "Ultraviolet-induced cell death blocked by a selenoprotein from a human dermatotropic poxvirus", <u>Science</u> ,279(5347), (Jan. 2, 1998),102-5	
		SNYDER, P. M., et al., "Serum and Glucocorticoid-Regulated Kinase Modulates Nedd4-2-Mediated Inhibition of the Epithelial NA <sup>+</sup> Channel", <u>The Journal of Biological Chemistry</u> , 277(1), (2002),5-8	
		SONNTAG, FLORIAN , et al., "Adeno-associated Virus Type 2 Capsids with Externalized VP1/VP2 Trafficking Domains Are Generated Prior to Passage through the Cytoplasm and Are Maintained until Uncoating Occurs", <u>Journal of Virology</u> , Vol. 80, No. 22,(November 2006),11040-11054	
		SPINDLER, B. , et al., "Characterization of Early Aldosterone-induced RNAs identified in A6 Kidney Epithelia", <u>Pfluegers Archiv</u> , Vol. 434, Springer Verlag, Berlin, DE XP001025924 ISSN: 0031-6768,(1997),323-331	
		STUTTS, M. J., et al., "Cystic fibrosis transmembrane conductance regulator inverts protein kinase A-mediated regulation of epithelial sodium channel single channel kinetics.", <u>J. Biol. Chem.</u> , 272(22), (1997),14037-14040	
		TEOH, M. L., et al., "Tumorigenic poxviruses up-regulate intracellular superoxide to inhibit apoptosis and promote cell proliferation", <u>J Virol.</u> , 79(9), (May, 2005),5799-811	
		THOMAS, C. P., et al., "Genomic Organization of the 5' End of Human B-ENaC and Preliminary Characterization of its Promoter", <u>Am. J. Physiol. Renal Physiol.</u> 282, (2002),F898-F909	
		THRASHER, A J., et al., "Generation of recombinant adeno-associated virus (rAAV) from an adenoviral vector and functional reconstitution of the NADPH-oxidase", <u>Gene Therapy</u> , Macmillan Press Ltd., Basinstoke, GB, Vo. 2, 1995, pages 481-485, XP000651495, (1995),5	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

<b>Application Number</b>	10/815,262
<b>Filing Date</b>	March 31, 2004
<b>First Named Inventor</b>	Engelhardt, John
<b>Group Art Unit</b>	1633
<b>Examiner Name</b>	Hill, Kevin

Sheet 11 of 11

Attorney Docket No: 875.074US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		TRISCHLER, M. , et al., "Biochemical analysis of distinct Rab5- and Rab11-positive endosomes along the transferrin pathway.", <u>J Cell Sci.</u> , 112 ( Pt 24), (Dec., 1999),4773-4783	
		VEMA, I. M., et al., "Gene Therapy - Promises, Problems and Prospects", <u>Nature</u> , 389, (1997),239-242	
		XIA, W. , et al., "Presenilin 1 regulates the processing of beta-amyloid precursor protein C-terminal fragments and the generation of amyloid beta-protein in endoplasmic reticulum and Golgi", <u>Biochemistry</u> , 37(47), (Nov. 24, 1998),16465-71	
		YAN, Z. , et al., "Distinct Classes of Proteasome-Modulating Agents Cooperatively Augment Recombinant Adeno-Associated Virus Type 2 and Type 5-Mediated Transduction from the Apical Surfaces of Human Airway Epithelia", <u>Journal of Virology</u> , 78, (Mar., 2004),2863-2874	
		ZENTNER, M. D., "The Amiloride-Sensitive Epithelial Sodium Channel $\alpha$ -Subunit is Transcriptionally Down-Regulated in Rat Parotid Cells by the Extracellular Signal-Regulated Protein Kinase Pathway", <u>The Journal of Biological Chemistry</u> , 273(46), (1998),30770-30776	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional) <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached